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MIPR NUMBER: 92MM2549

TITLE: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents

PRINCIPAL INVESTIGATOR: LTC Donald R. Skillman

CONTRACTING ORGANIZATION: Fitzsimons Army Medical Center Aurora, Colorado 80045-5001

REPORT DATE: April 1996

TYPE OF REPORT: Final

PREPARED FOR: Commander

U.S. Army Medical Research and Materiel Command Fort Detrick, Frederick, Maryland 21702-5012

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| 13. ABSTRACT (Maximum 200 | AMC Infectious Disease | Service is closing (| 3Ø June 1996. The clinical drug | | |
| trials referred to FAMC for HIV/AIDS patients have been terminated and all patients have been referred either | | | | | |
| to other military treatment facilities, the Veterans Administration, or private health care providers. No MIPR | | | | | |

funds were expended in any of these trials.

FAMC enrolled approximately 700 patients in the natural history study since its beginning. FAMC has stored, on site, almost 56,000 frozen plasma/serum/cell samples of HIV from 1986 to the present. These frozen specimens will be sent to CPT Douglas Mayer at WRAIR, to be stored at a facility designated by him for future scientific purposes. The data base, has been previously integrated into the central MMCAR data base, updated information will be sent with the frozen specimens and patient records. Patient histories had been routinely sent to Sociometrics, who we understand had been collecting this data for the U.S. Armed Forces. Copies of patient records will be sent to CPT Mayer (or his designee) for ready access to clinical information, should it be needed.

Some statistical information is being evaluated by Susan Y. J. Zhou at the Henry M. Jackson Foundation.

Results and significance of this MIPR will be decided at some time in the future. The purpose of the MIPR was to collect and save specimens of HIV from Military beneficiaries, and others included in the protocol, so that material would be available for future research.

| 14. SUBJECT TERMS Drug Resistance, HIV, | 15. NUMBER OF PAGES 4 | | |
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| 17. SECURITY CLASSIFICATION OF REPORT | 18. SECURITY CLASSIFICATION OF THIS PAGE | 19. SECURITY CLASSIFICATION OF ABSTRACT | 20. LIMITATION OF ABSTRACT |
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FOREWORD

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In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

PI - Signature

Date

FINAL REPORT

1. MIPR No. 92MM2549

2. Report Date:

15 May 1996

3. Reporting Period from:

1 April 1992

to:

3Ø April 1996

4. P.I.: Donald R. Skillman, LTC, MC 5. Phone (3Ø3) 361-8Ø14

DSN 943-8Ø14

6. Agency/ Address: Fitzsimons Army Medical Center

MCHG-MDI (Infectious Disease Service)

Aurora, CO 80045-5001

7. Project Title:

Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV

Infected Individuals Taking Antiretroviral Agents.

FAMC Protocol # 91/300

8. Current Staff, with percentage of effort on each project:

Donald R. Skillman, LTC, MC

Erin Palestro, R.N.

100%

9. MIPR Expenditures to date:

Personnel

\$111,841.

Supplies

\$352,327.

Travel

\$ 50,349.

Other

\$ 12,023.

Equipment

\$ 76,492.

Contracts

\$ 77,361.

Total

\$680,393.